



Patient Information Sheet

Formoterol fumarate inhalation powder (marketed as Foradil Aerolizer)

This is a summary of the most important information about Foradil. For details, talk to your healthcare professional.

FDA ALERT [11/2005] In some patients with asthma, medicines called “long-acting beta-agonists” (LABA) may increase the chance of death from asthma problems.

FDA has asked companies that make long-acting beta-agonists, including Foradil Aerolizer, to give special warnings to healthcare professionals and patients about these possible risks.

Because LABAs, such as Foradil Aerolizer, may increase the chance of asthma death in some people:

- **It should not be the first medicine prescribed for your asthma.**
- **It should not be the only medicine prescribed for your asthma.**
- **It should always be used with another asthma-controller medicine, and only after another asthma-controller medicine, such as a low-to-medium dose of an inhaled corticosteroid, has not controlled your asthma.**

This information reflects FDA’s current analysis of data available to FDA concerning this drug. FDA intends to update this sheet when additional information or analyses become available.

What Is Foradil?

Foradil Aerolizer is a medicine called a “long-acting beta-agonist” and is a long-acting bronchodilator medicine. Bronchodilator medicines help to relax the muscles around the airways in your lungs. Wheezing happens when the muscles around the airways tighten. This makes it hard to breathe. In severe cases, wheezing can stop your breathing and cause death if not treated right away.

Foradil Aerolizer does NOT relieve sudden breathing problems. Always have a short-acting bronchodilator medicine with you to treat sudden breathing problems.

Foradil Aerolizer is used for:

Asthma

- Foradil Aerolizer is used long-term, twice-a-day, to control and prevent symptoms of asthma in adults and children ages 5 and older.

Because Foradil Aerolizer can increase the chance of death from asthma, it is not for adults and children with asthma who:

- are well controlled with other asthma-controller medicines such as low-to-medium doses of inhaled corticosteroids
- need only short-acting bronchodilators once in awhile

Exercise-Induced Bronchospasm (EIB)

Foradil Aerolizer is used to prevent wheezing (bronchospasm) during exercise in adults and children 5 years of age and older.

Chronic Obstructive Pulmonary Disease (COPD)

Foradil Aerolizer is used long-term, twice-a-day in controlling wheezing (bronchospasm) in adults with COPD.

What Are The Risks?

The following are the major potential risks and side effects of Foradil Aerolizer therapy. However, this list is not complete.

Foradil Aerolizer may worsen your breathing problems. See FDA Alert.

Other possible side effects with Foradil Aerolizer include:

- allergic reactions including, rash, hives, and swelling of the face, mouth, and tongue
- increased blood pressure
- fast and irregular heartbeat
- chest pain
- headache
- tremor
- nervousness
- dry mouth
- muscle cramps
- nausea
- dizziness, tiredness
- low blood potassium
- high blood sugar
- trouble sleeping





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Tell your healthcare professional about any side effect that bothers you or that does not go away.

What Should I Tell My Healthcare Professional?

Before you start using Foradil Aerolizer, tell your healthcare professional if you:

- have heart problems
- have high blood pressure
- have seizures
- have thyroid problems
- have diabetes
- have liver problems
- are pregnant or planning to become pregnant. It is not known if Foradil may harm your unborn baby.
- are breastfeeding. It is not known if Foradil passes into your milk and if it can harm your baby.

Can Other Medicines or Food Affect Foradil?

Foradil Aerolizer and certain other medicines can interact with each other. Tell your healthcare professional about all the medicines you take including prescription and non-prescription medicines, vitamins, and herbal supplements. Some medicines may affect how Foradil Aerolizer works or Foradil Aerolizer may affect how your other medicines work. Know the medicines you take. Keep a list of them with you to show your healthcare professional.

How Do I Use Foradil Aerolizer?

Read the step-by-step instructions for “How to Use Foradil” that comes with the medicine. Do not use Foradil Aerolizer unless your healthcare professional has taught you and you understand everything.

Use Foradil Aerolizer exactly as prescribed. Do not use Foradil more often than prescribed.

- Do not change or stop any of your medicines to control or treat your breathing problems. Your healthcare professional will adjust your medicines as needed.
- Make sure you always have a short-acting bronchodilator medicine with you. Use your short-acting bronchodilator if you have breathing problems between doses of Foradil Aerolizer.

Call your healthcare professional right away if:

- your breathing problems worsen while you are taking Foradil Aerolizer
- you need to use your short-acting bronchodilator more often
- your short-acting bronchodilator does not work as well for you at relieving symptoms
- you need to use 4 or more inhalations of your short-acting bronchodilator for 2 or more days in a row
- you use 1 whole canister of your short-acting bronchodilator medicine in less than 8 weeks time

